

**REMARKS**

Claims 124-134 are pending in the application. Claims 128-134 are withdrawn by the examiner. Claims 124-127 are currently under examination. Claims 124, 126 and 127 are amended for clarity by replacing the term "pre-annealing" with "pre-heating". The amendments to the claims are supported by the specification as discussed herein. Therefore, no new matter is introduced. The office action is discussed below:

***Response to Arguments and Rejections Maintained:***

***Written Description Rejection:***

On pages 2-3 and 5-6 of the Office Action, the examiner has maintained the alleged rejection of claims 124-127 for various written description-related reasons.

On page 2 of the Office Action, the examiner opines that the instant claim language is not supported by the disclosures of 08/600,744 or 08/726,313 and thus not entitled to the earlier priority dates thereof. Applicants respectfully disagree with the examiner and traverse the rejection for the reasons discussed herein.

On pages 2-3 and 5-6 of the Office Action, the examiner repeated the same arguments that the specification does not mention "pre-annealing" or the temperatures for "pre-annealing." The examiner interprets that the disclosed MIR method teaches melting the UHMWPE, which is not considered by the examiner to be equivalent to "pre-annealing", as set forth in the instant claims, or to "preheating", as disclosed in the WIR methods in the instant specification.

In response to the arguments, as filed on February 21, 2008, the examiner admitted that the specification, Example 3, page 41, disclose "pre-heating" followed by irradiation and then followed by cooling to room temperature. However, according to the examiner, the process in Example 3 does not disclose a "pre-annealing" step before irradiation.

Applicants disagree with the examiner and point out that the term "pre-heating" is generally regarded as "pre-annealing" in the art, see for example, the Saum '540 patent, col. 6, lines 34-41, wherein the UHMWPE was subjected to "pre-annealing", i.e., subjected to "pre-heating" to a temperature of 280°C to 355°C, which are temperatures above the melting point of the UHMWPE. Applicants reiterate that Example 3, at page 41, discloses that the temperature varied "between 200°C at the base to 175°C at the top.... [and] was held at these temperatures for a period of 30 minutes before starting the irradiation." The heating was continued until "[a]fter irradiation, the heating was stopped and the cup was allowed to cool to room temperature." The specification, thus clearly discloses "pre-annealing" or "pre-heating" for a period of time "greater than 30 minutes", because the heating continued until after irradiation and then cool slowly (which satisfies examiner's asserted definition of "annealing" or "pre-annealing" (see page 2 of the Office Action of September 28, 2006) and is also consistent with the disclosure of Saum *et al.*, column 6, lines 34-46 . Therefore, the specification has full support for the claim recitation of the term "pre-annealing."

However, in order to expedite the prosecution, applicants amend the claims 124, 126 and 127 to recite the term "pre-heating" instead of "pre-annealing", which essentially refers to the same process step, as discussed above.

With respect to the recitation a "period of time greater than 30 minutes", the examiner interprets that the disclosure on page 30 of a time period of about 30 minutes to about 2 hours is a description of the time period for maintaining the UHMWPE above the melting temperature before irradiation in the MIR embodiment. The examiner intends to interpret that MIR process does not involve a "pre-heating" or "pre-annealing" step. However, admits that there is a support for the time period for maintaining the UHMWPE above the melting temperature, which essentially is the process step of "pre-heating" or "pre-annealing", which requires maintaining the UHMWPE at a desired temperature.

Applicants believe that the examiner has not recognized that the specification on page 30, lines 8-12 clearly describes that "the heating is maintained so to keep the

polymer at the preferred temperature for about 5 minutes to about 3 hours, and more preferably for about 30 minutes to about 2 hours. The UHMWPE is then irradiated with gamma irradiation or electron irradiation.” Therefore, it is clear that the “heating” or “pre-heating” or “pre-annealing” of the UHMWPE was maintained (annealed) for a “period of time greater than 30 minutes” prior to irradiation.

On page 3 of the Office Action, the examiner asserts that there is no recited order of steps with respect to “pre-annealing”, irradiation, and quenching. According to the examiner, there is no cooling step as a predetermined rate is recited and it is not clear when the “pre-annealing” starts or stops. Again, applicants disagree with the examiner and refer to above clarification that the steps as recited in the claimed methods are clear to one skilled in the art and involve “pre-heating” or “pre-annealing”, irradiation, and quenching. Applicants do not agree with the examiner that a cooling step as a predetermined rate is required to clarify when the “pre-annealing” starts or stops in the methods according to claims 124, 126, or 127. However, applicants do agree that the cooling step recited in claim 125 is not a part of the “pre-heating” or “pre-annealing” step recited in claim 124.

In view of the above clarifications and amendments to claims 124, 126 and 127, applicants request withdrawal of the written description rejection.

***Anticipation and Obviousness Rejections:***

On pages 4 and 6-7 of the Office Action, the examiner has maintained the alleged anticipation and obviousness rejections of claims 124-127 in view of Shalaby (the ‘411 patent) and Sun (the ‘049 patent), respectively.

The examiner agreed that Shalaby *et al.* teach melting UHMWPE powder in contact with UHMWPE fibers to obtain a reinforced composite by heating for a time necessary to melt the powder and then cooling the composite. Accordingly, applicants submit that Shalaby discloses the melting of ultrahigh molecular weight polyethylene (UHMWPE) powder for consolidation followed by the production of UHMWPE fibers to

reinforce UHMWPE composites. It is clearly noted in the '411 patent that the "polymer-fiber construct" is made after melting the UHMWPE powder to reduce its melting point so that the fibers do not melt. That is, the "UHMWPE powder cannot be used directly in making composites because its melting point temperature is very close to that of the fiber so that fibers might also melt" (see the '411 patent, Example 1, col. 6, lines 54-57). Therefore, Shalaby does not disclose a method of making an UHMWPE "construct polymer-fiber" by melting or pre-heating or pre-annealing the UHMWPE "construct polymer-fiber." Applicants point out that the examiner has not addressed this issue.

Moreover, according to the '411 patent melting of the UHMWPE (when it is in a powder form) component of the final product was performed in order to avoid melting of the fibers of the product. Hence, the heating or melting to allow free radicals to recombine in the final product is not taught in the '411 patent, because, the final product made by Shalaby were not processed to recombine the free radicals in the final product by quenching or any other methods. Thus, Shalaby *et al.* would not be expected to result in recombination of free radicals. Accordingly, Shalaby's finished product will possess free radicals, and thus be susceptible to oxidation, as Shalaby disclosed at column 4, lines 56-58. Therefore, Shalaby (the '411 patent) process cannot yield a product made by any of the claimed processes.

The examiner opines that radiation causes free radicals to form that are then "quenched" by crosslinking in the presence of acetylene. The examiner asserts that the claim recitation "and quenching residual free radicals...preform" does not limit the manner of quenching free radicals and relies on Shalaby description of "high energy radiation crosslinks the UHMWPE" (refers to column 6, lines 1-7). The examiner believes, Shalaby teaches that the composite can be irradiated in the presence of acetylene which would be expected to enhance crosslinking.

Applicants respectfully disagree with the examiner and submit that Shalaby mentions about "high energy radiation", which refers to sterilization dose of 2.50 Mrads, which is a "low dose irradiation" or "sterilization irradiation." More specifically, Shalaby discloses "a dose of 2.50 Mrads in three different gas environments, namely, air,

nitrogen (practically pure), and acetylene" (see Shalaby Example 5, also see Example 7 and Figure 6). Such "low dose irradiation" or "sterilization irradiation" would generate residual free radicals and would not be "quenching residual free radicals in the ultrahigh molecular weight polyethylene preform subsequent to the irradiating step", as required by the claimed method. In this context, applicants invite the examiner to consider the MPEP § 2111 that:

"The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification" as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364, [70 USPQ2d 1827] (Fed. Cir. 2004)."

Therefore, based on Shalaby disclosure, one skilled in the art would not use a radiation dose higher than Shalaby's "sterilization irradiation" (for example, a gamma radiation dose of 2.50 Mrads) to arrive at the claimed invention, because, as clarified above, such "low dose irradiation" or "sterilization irradiation" would generate residual free radicals and would not be "quenching residual free radicals.

Thus, Shalaby and/or Sun does not disclose the claimed methods. As discussed above, applicants submit that the "low dose irradiation" or "sterilization irradiation" of Shalaby or Sun would generate residual free radicals and would not be quenching residual free radicals in the ultrahigh molecular weight polyethylene preform subsequent to the irradiating step, as required by the claimed method. Therefore, Shalaby and/or Sun does not anticipate the claimed methods nor make the claimed methods obvious. Accordingly, withdrawal of the anticipation and obviousness rejections of claims 124-127 are solicited.

#### ***Double Patenting Rejections:***

On pages 4 and 8-10 of the Office Action, the examiner also has maintained the provisional rejection of claims 124-127 under the judicially created doctrine of obviousness-type double patenting allegedly as being unpatentable over pending

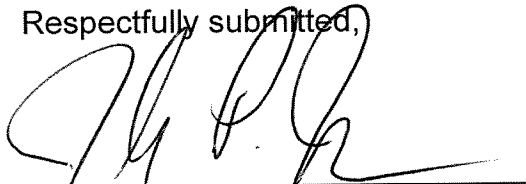
claims of co-pending applications serial nos. 10/948,440, 10/197,209, 10/696,362, 10/901,089 and 10/197,263.

Applicants remind the examiner that none of the cited co-pending applications have received a notice of allowance. Therefore, the merits of this provisional rejection need not be discussed at this time. See MPEP § 822.01.

**REQUEST**

Applicants submit that claims 124-127 are in condition for allowance, and respectfully request favorable consideration to that effect. The examiner is invited to contact the undersigned at (202) 416-6800 should there be any questions.

Respectfully submitted,

  
\_\_\_\_\_  
John P. Isacson  
Reg. No. 33,715

May 28, 2009

Date

PROSKAUER ROSE LLP  
1001 Pennsylvania Avenue, N.W.  
Suite 400 South  
Washington, D.C. 20004  
Phone: 202-416-6800  
Fax: 202-416-6899  
Customer No. 61263